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### **FAX**

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Examiner N. Alonzo	703-872-9306	Commissioner for Patents
Art Unit 1632		Alexandria, Virginia
571-272-2910	·	
John K. McDonald, Ph.D.		7
FROM		PAGES (WITH COVER)
7770		43150-286808
REFERENCE NO		CLIENT/MATTER NO.

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### **COMMENTS**

The facsimile confirmation of the Patent Office imprinted hereon will acknowledge receipt of:

Serial No: 10/618,839 Filing Date: July 14, 2003

Inventor: J. David LAMBETH et al.

For: Methods and Transgenic Mouse Model for Identifying and Modulating Factors Involved

in the Production of Reactive Oxygen Intermediates

Papers Submitted: Transmittal; Response to Restriction Requirement

Docket No.: 43150/286808 (05501-0211)

Date Mailed July 1, 2004 Atty/Sec: JKM:SCM:ckf

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**PATENTS** 

# IN THE U.S. PATENT AND TRADEMARK OFFICE

In re Application of: J. David Lambeth, et al.

Docket No. 05501-0211 (43150-286808)

Filed:

Serial No. 10/618,839

For:

July 14, 2003
METHODS AND TRANSGENIC MOUSE MODEL FOR IDENTIFYING AND

MODULATING FACOTRS INVOLVED IN THE PRODUCTION OF REACTIVE

**OXYGEN INTERMEDIATES** 

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450 OFFICIAL

Sir:

Transmitted herewith is a paper in the above-identified application.

$\boxtimes$	Response	to	Restriction	Requirement

Applicant claims small entity status.

No additional fee is required.

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	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE	ADDIT. FEE	RATE	ADDIT. FEE
TOTAL	16	MINUS	26=	0	х9	\$	x18	\$
INDEP.	1	MINUS	3=	0	x43	\$	x86	\$
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				TOTAL ADDITIONA	L FEE	\$0		\$

A check in the amount of \$\sis atta	ched.
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The Commissioner is hereby authorized to charge any additional fees required under 37 CFR §1.16, or credit any overpayment, to Account No. 11-0855. A duplicate copy of this sheet is enclosed.

I hereby certify that this correspondence is being sent by facsimile transmission to the Commissioner for Patents to 703-872-9306 attention Examiner Norma C. Alonzo on July 1, 2004.

John K. MoDonald, Ph.D.

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ATLLIB02 162179.1

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PATENTS

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	
J. DAVID LAMBETH	
Serial No. 10/618,839	Art Unit: 1632
Filed: <b>July 14, 2003</b>	) ) Examiner: N. Alonzo
For: METHODS AND TRANSGENIC MOUSE MODEL FOR IDENTIFYING AND MODULATING FACOTRS INVOLVED	) ) )
IN THE PRODUCTION OF REACTIVE OXYGEN INTERMEDIATES	) )

## RESPONSE TO RESTRICTION REQUIREMENT

Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

### Dear Sir:

Responsive to the Office Action mailed on June 1, 2004, please consider the following remarks.

It is believed that no fee is required with this submission. However, should a fee be required, the Commissioner is hereby authorized to charge the fee to Deposit Account No. 11-0855.

Remarks begin on Page 2 of this paper.

John K. McDonald, Ph.D. - Reg. 42,860

I hereby certify that this correspondence is being sent by facsimile transmission to the Commissioner for Patents to 703-872-9306 attention Examiner Norma C. Alonzo on July 1, 2004.

Response to Restriction Requirement Serial No. 10/618,839 Page 2 of 5

#### Remarks

In the Restriction Requirement mailed June 1, 2004, the Examiner divided the claims into 15 groups:

Group I: Claims 1-6, 9-17 and 26 drawn to a transgenic non-human animal comprising the sequence of SEQ ID NO:1, a cell or cell line derived from said transgenic non-human animal and a method of using said transgenic non-human animal. (Class 800, subclass 8)

Group II: Claims 1-5, 9-17 and 26 drawn to a transgenic non-human animal comprising the sequence of SEQ ID NO:3, a cell or cell line derived from said transgenic non-human animal and a method of using said transgenic non-human animal. (Class 800, subclass 8)

Group III: Claims 1-5, 9-17 and 26 drawn to a transgenic non-human animal comprising the sequence of SEQ ID NO:5, a cell or cell line derived from said transgenic non-human animal and a method of using said transgenic non-human animal. (Class 800, subclass 8)

Group IV: Claims 1-5, 9-17 and 26 drawn to a transgenic non-human animal comprising the sequence of SEQ ID NO:7, a cell or cell line derived from said transgenic non-human animal and a method of using said transgenic non-human animal. (Class 800, subclass 8)

Group V: Claims 1-5, 9-17 and 26 drawn to a transgenic non-human animal comprising the sequence of SEQ ID NO:9, a cell or cell line derived from said transgenic non-human animal and a method of using said transgenic non-human animal. (Class 800, subclass 8)

Group VI: Claims 1-5, 9-17 and 26 drawn to a transgenic non-human animal comprising the sequence of SEQ ID NO:11, a cell or cell line derived from said

Response to Restriction Requirement Serial No. 10/618,839 Page 3 of 5

transgenic non-human animal and a method of using said transgenic non-human animal (Class 800, subclass 8)

Group VII: Claims 1-5, 9-17 and 26 drawn to a transgenic non-human animal comprising the sequence of SEQ ID NO:13, a cell or cell line derived from said transgenic non-human animal and a method of using said transgenic non-human animal. (Class 800, subclass 8)

Group VIII: Claims 7-8 and 19-20 drawn to a transgenic non-human animal comprising a transgene encoding a NADPH oxidase enzyme or dual oxidase enzyme and further comprising a nonsense mutation in a murine adenomatous polyposis coli gene, and a method for using said transgenic non-human animal. (Class 800, subclass 8)

Group IX: Claims 21-25 drawn to a vector comprising a transgene wherein the transgene is SEQ ID NO:1, a cell containing the said vector. (Class 435, subclass 325)

Group X: Claims 21-25 drawn to a vector comprising a transgene wherein the transgene is SEQ ID NO:3, a cell containing the said vector. (Class 435, subclass 325)

Group XI: Claims 21-25 drawn to a vector comprising a transgene wherein the transgene is SEQ ID NO:5, a cell containing the said vector. (Class 435, subclass 325)

Group XII: Claims 21-25 drawn to a vector comprising a transgene wherein the transgene is SEQ ID NO:7, a cell containing the said vector. (Class 435, subclass 325)

Group XIII: Claims 21-25 drawn to a vector comprising a transgene wherein the transgene is SEQ ID NO:9, a cell containing the said vector. (Class 435, subclass 325)

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Group XIV: Claims 21-25 drawn to a vector comprising a transgene wherein the transgene is SEQ ID NO:11, a cell containing the said vector. (Class 435, subclass 325)

Group XV: Claims 21-25 drawn to a vector comprising a transgene wherein the transgene is SEQ ID NO:13, a cell containing the said vector. (Class 435, subclass 325)

In response, Applicants elect Group I directed to a transgenic non-human animal comprising the sequence of SEQ ID NO:1, a cell or cell line derived from said transgenic non-human animal, and a method of using said transgenic non-human animal. This election is made with traverse.

### The Current Restriction Requirement is Improper

The current restriction requirement divides a transgenic animal and a vector into fifteen inventions. Claims 1-5, 7-20, 21-25 and 26 are all generic and do not specify a transgene. The current restriction attempts to impose limitations on the claims through the vehicle of restriction requirement.

At the very most, the claims should be restricted to two groups of claims for prosecution, (claims 1- 20 and 26 are directed to a transgenic animal and claims 21-25 are directed to a vector comprising a transgene) with an election of species for the transgene. The Manual of Patent Examining Procedure states "[i]f the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions." (MPEP 803)

Rejoinder of the claims would not present an undue burden for the Examiner to search because groups I-VIII are all in the same class/subclass (Class 800, subclass 8). Similarly, groups IX-XV are also in the same class/subclass (Class 435, subclass 325).

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Applicants note that claim 18 was not included in any of the fifteen groups of claims cited by the Examiner.

Applicants were also required to elect one species of promoter for search purposes on the understanding that upon allowance of a generic claim, claims to the additional species will be considered if they are written in dependent form or otherwise include all the limitations of the allowed generic claim. In response, Applicants elect the CX1 promoter.

Rejoinder and examination of the claims is respectfully solicited.

Respectfully submitted,

John K. McDonald, Ph.D

Reg. No. 42,860

### KILPATRICK STOCKTON LLP

1100 Peachtree Street Suite 2800 Atlanta, Georgia 30309-4530 Tel. (404) 745-2470 Attorney Docket No. 05501-0211 (43150-286808)